

BME 1550H: Cellular and Gene Therapy-Science, Manufacturing and Regulations

Description of the Course

This seminar/reading course is an interactive course designed to provide graduate students a basic understanding of latest developments in cellular, gene-modified cells and gene therapy, articulating basic science concepts and challenges in process development, scalability, quality control, safety, potency, and meeting evolving regulatory requirements. Each week, we will invite a leading key Opinion Leader to serve as a guest speaker to present a seminar on their respective field of research related to cellular and gene therapy, science, manufacturing, and regulation. The course is divided into **4 sub-categories: MSCs, iPSCs, Immunotherapy, GMP Manufacturing considerations** with 3 lectures on each subcategory. Each class will begin with two or three student presentations, where each student will present a paper assigned to them by the invited speaker (10 minutes per presentation). Following this, the invited speaker will give a 40-minute seminar on their research. The class will conclude with an in-depth discussion that integrates both the assigned papers and the speaker's seminar, during which each student is expected to ask at least one question.

A total of two hours will be dedicated to each session, which will include student presentations and the seminar by the Guest Speaker and a detailed discussion of the assigned papers led by the Guest Speaker and the Student Presenters. There will be 12 lectures (2 hours each for a total of 24 hours).

The lectures are held on Wednesdays from 1-3pm at the Woodsworth college (119 St.George Street), Room 120.

Course Specifications

Readings:

Up to three research articles (corresponding with the weekly Guest Speakers) will be circulated for students to critically review and prepare questions for a discussion led by the Guest Lecturer and the Student Presenters. Students are required to pose a minimum of one question as part of their participation mark (20%).

Research seminars presented by Guest Speakers:

40-minute seminar and remaining time for discussion

The Guest Speaker will present a research seminar and follow this with an in-depth discussion on three selected papers that speak to the state-of-the-art on MSCs, iPSCs, Immunotherapy, GMP Manufacturing. Students are required to attend these seminars and pose a minimum of 1 question.

Discussion Questions and Class Participation

Students are required to read the assigned readings and come prepared for a detailed discussion. The students are required to ask a minimum of one question during class. All students are

expected to **contribute to the discussion of the paper during class**. All students will be marked on their participation in class by the teaching assistant.

Presentation of Student-Selected Papers

Students will be randomly assigned to small groups after the first class (2–3 students per group) and given three research articles related to one of the 10 topics presented by the guest lecturers on MSCs, iPSCs, Immunotherapy, GMP manufacturing. Each student in the group will prepare a presentation on one of the assigned papers, which will be different from the topic they choose for their term paper.

Presentations will be a total length of 20-30 minutes combined (depending on the numbers of students in the group) and should include an introduction, a summary of the results, and most importantly a **critical** discussion of the findings. All students in a group must present, and grading will be done **individually** according to the rubric. After the combined presentations, there will be about 15–20 minutes of class discussion.

Marking of each student will be performed by course coordinators using the rubric on page 4; the oral presentation is worth 40% of the total mark. Detailed guidelines for presentations are included in the course description and in the rubric. Note, the topic selected for the presentation and term paper needs to be different. Students will have access to a computer and multimedia projector for the presentation; plan on approximately 1 minute per slide.

Term Paper

Maximum 7-8 pages double-spaced (page limit does not include references)

Students will be expected to write a **critical** review of one of the 10 research topics based on one or both papers assigned by the Guest Lecturer, selected by them on one of the lectures presented. The term paper topic should **not** be the same area as their oral presentation. The research review should be a critical appraisal of the current area of research, working beyond the two-three papers presented. The term paper is due on **April 8th at 11:59 pm**. Please note that no extensions will be given for the submission of the term paper. Term paper will be marked out of 40 – please see breakdown under evaluation criteria and in the attached rubric.

Term Paper Specifications:

Paper must be typed, double-spaced, 12-point font size, preferably Arial or Times New Roman font with 1-inch margins all around. All pages should be numbered. Inserting figures/tables is not mandatory, but if you do, it should be included within the limit of 7-8 pages. Please do not insert more than 2 figures or tables. References should be included on an additional page, with a maximum of 25. The term paper should include the following sections: Abstract, Introduction, Methods, Results, Discussion, and References.

Abstract:

The abstract consists of 200-250 words in which you summarize the topic, the specific subject of the research problems, the major findings, and the conclusions.

Introduction:

Provide background on the research topic, summarize the present state of knowledge of the topic, and provide a clear description of the nature of the research problem that will be investigated in the Results section. Be selective with the background information that you include, as you are not writing a textbook. This section should be about 1-1½ pages long.

Methods:

Briefly, describe methods used in the current studies using subheadings. This section should be about 1-1½ pages long. Indicate the methodology used for the experiments, but do not go into the details of how the experiments were done. You can use subheadings for the different topics discussed. You should provide a critical review of this research methodology.

Results:

Present in your own words main relevant results on the research topic. You can use subheadings for the different topics discussed. You should provide a critical review of the results. Max. 2 pages.

Discussion:

Summarize the major new findings, discuss their relevance to the current literature, and draw the major conclusions. You should discuss similarities, discordant, or complementary results from the articles, and your own literature review of the field. This is a critical review, and you should illustrate your critical conceptual thinking skills in this section. You may find including your own table or schematic diagram helpful with your discussion. You should also briefly propose future studies relevant to the findings and or discuss limitations/challenges.

References:

References should be numbered (1, 2, 3...) as they appear in the text – limit to 25 references.
Use the following format:

Viswanathan, S , Shi, Y, Galipeau, J, Krampera, M, Leblanc K, Martin, I, Nolte, J D G Phinney , D.G, Sensebe, L 9: **Mesenchymal stem versus stromal cells: International Society for Cell & Gene Therapy (ISCT®) Mesenchymal Stromal Cell committee position statement on nomenclature.** *Cytotherapy* 2019, 21(10):1019-1024

If you are using reference management software, use the “American Journal of Pathology” format. If textbooks are used as references, first list all the authors as shown in the example above followed by the chapter title, title of the textbook, edition, year of publication and page numbers used.

Evaluation Criteria**1) 20% - Class Participation**

Students are required to attend the classes and pose at least one question each lecture.

2) 40% Presentation (Total = 40 marks)

- Presentation layout: 5
- Presentation style: 5
- Interpretation of results and critique: 30

3) 40% Term Paper (Total = 40 marks)

- Discussion including references: 20 marks
- Results and Methodology: 12 marks
- Language and references: 8 marks
- **Due date: April 8th, 2026**

Winter 2026 Course Schedule

Date	Time	Speakers	Topic
Week 1 Jan 7	Room: WW120 13:00- 15:00	Dr. Sara Nunes Vasconcelos And Dr. Sowmya Viswanathan	Introductory Lecture (No assigned papers)
Week 2 Jan 14	13:00- 15:00	Dr. Sowmya Viswanathan	Regulatory Overview - Health Canada vs. FDA/EMA regulations for cell and gene therapies (No assigned papers)
Week 3 Jan 21	13:00- 15:00	Dr. John Davies	MSC Introduction (Student Presentations Start)
Week 4 Jan 28	13:00- 15:00	Dr. Sowmya Viswanathan	Advancing Osteoarthritis Therapy using MSCs
Week 5 Feb 4	13:00- 15:00	Dr. Sara Nunes Vasconcelos	PSC Overview
Week 6 Feb 11	13:00- 15:00	Dr. Shinichiro Ogawa	Repairing and Rescuing Bile Ducts
Week 7 Feb 18	READING WEEK – NO LECTURE		
Week 8 Feb 25	13:00- 15:00	Dr. Michael Laflamme	Scaling Stem Cell Manufacturing
Week 9 March 4	13:00- 15:00	Dr. Sonya MacParland	Engineering Liver and Immune Dynamics
Week 10 March 11	13:00- 15:00	Dr. Neil Blackburn	Use of CAR-T cells in clinical trials

Week 11 March 18	NO LECTURE		
Week 12 March 25	13:00- 15:000	Dr. Ralph DaCosta	NK and gamma delta ($\gamma\delta$) T cells
Week 13 April 1	13:00- 15:00	Dr. Liz Csaszar	Next-Generation Cellular Immunotherapies (Last Student Presentations)
Week 14 April 8	13:00- 15:00	Dr. Linh Nguyen	Insights into TIL Therapy Efficacy
	TERM PAPER DUE AT 11:59 PM		

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